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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,874	12/22/1999	MARC MEHRZAD JALISI	ACS-58267 (1700X)	6721

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EXAMINER	
THOMPSON, KATHRYN L	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/470,874	JALISI ET AL.	
	Examiner	Art Unit	
	Kathryn L Thompson	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 13-25, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fariabi (US 5,636,641) in view of Fagan (US 5,720,300). Fariabi teaches a heat-treated elongate member/guide wire comprising a composite elongate core, the composite elongate core formed in part of an aged hardened material and in part of a superelastic material, a flexible body disposed at a distal end of the distal section, wherein the aged hardened material and superelastic material extend from the proximal section to at least substantially underneath the flexible body (See Figure Below), the distal section having a proximal portion and a tapered distal portion, the aged hardened material comprising of at least two materials selected from the group consisting of nickel, cobalt, molybdenum, chromium, tungsten, and iron (Column 3, Lines 49-51, 64-65). Fariabi does not teach that the elongate core is formed in part of a precipitation hardened material and in part of a superelastic material. Fagan teaches of an elongate core formed of a precipitation hardened material (Column 4, Lines 54-58). Fagan discloses that in order to avoid kinking of a guidewire it is necessary to have a desirable material that has equal compressive and tensile yield stresses. Such a desirable material, teaches Fagan, is made of a precipitation hardened material (Column 4, Lines 41-58). It would be obvious to one with ordinary skill in the

art to use the teachings of Fagan to modify the invention of Fariabi to create a heat-treated elongate member formed at least in part of acomposite elongate core, the composite elongate core formed in part of a precipitation hardened material and in part of a superelastic material, in order to create the necessary stiffness and push provided by the precipitation hardened material of the elongate core member and the desirable flexibility provided by the superelastic material of the elongate core member (Column 5, Lines 65-67; Column 6, Lines 1-10).

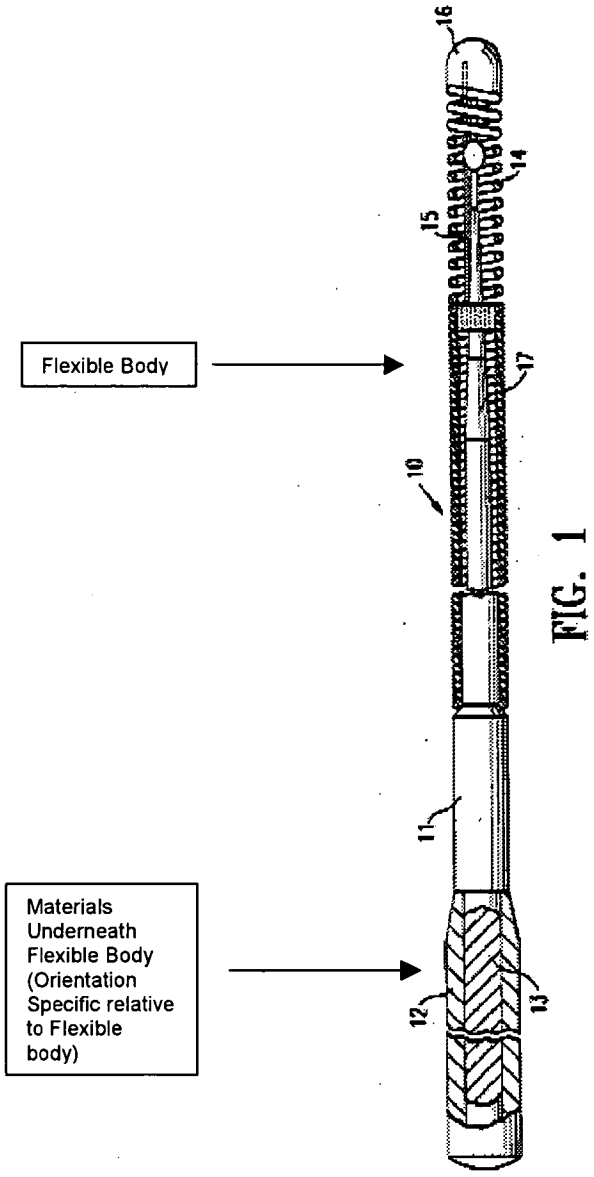

FIG. 1

Fariabi discloses a high strength alloy containing cobalt, nickel, and chromium and particularly to a composite product having a portion formed of the high strength colbalt-nikel-chromium alloy and a portion formed of pseudoelastic alloy such as NiTi alloy (Column 2, lines 16-19). Fariabi further discloses that one embodiment of the invention is an elongated member formed at least in part, of alloy comprising about 28%-65% cobalt, about 2%-40% nickel, about

5%-35% chromium an up to about 12% molybdenum. Other alloying components include up to 20% tungsten, 20% iron and 3% manganese. The alloy may also contain inconsequential amounts of other alloying constituents, as well as impurities, typically less than 0.5% each (Column 2, lines 21-30). Fariabi further states that in another embodiment of the invention, the cobalt-nickel-chromium alloy is formed into a composite structure with a NiTi alloy (Column 2, lines 51-53).

In Figure 1, Fariabi shows the distal section (17) of the core member (11), which is disposed primarily within the coil (14), and is tapered to sequentially smaller diameters to provide gradually increasing flexibility along the length of the distal portion of the guidewire (10). Figure 2 depicts a guidewire (30) with a construction wherein the tapered distal section (31) of the core member (32) extends to the plug (33) which connects the distal end of the core member to the distal end of the helical coil (34) disposed about the distal section of the core member. The proximal section (35) of the core member (32) is of composite construction with a sheath (36) of high strength CoNi-Cr alloy and an inner member (37) of a pseudoetastic NiTi alloy. The high strength sheath (36) is removed from the core member to form the tapered distal section (31) to increase the flexibility of the distal section of the guidewire (30).

With regard to claims 2-7, 9, and 10, Fariabi does not teach a composite elongate core having a modulus of elasticity of at least 9,000,000 psi, 12,000,000 psi_1 and 15,000,000 psi and an ultimate tensile strength of at least 150 ksi, 180 ksi, and 200 ksi. Fariabi also does not teach of a precipitation hardenable material such as precipitation hardenable stainless steel and chromium-nickel based single stage martensitic precipitation hardenable stainless steel. Fagan teaches an elongate member (52,56) formed at least in part of a composite elongate core (50)

formed at least in part of a precipitation hardened material such as an alloy composed of nickel, cobalt, molybdenum, and chromium (MP35N and Eligiloy) having a small amount of iron (Column 5, lines 2-4), 455PH stainless steel or stainless steel alloy 1 RK91. 455PH is known to be a chromium-nickel based single stage martensitic precipitation hardenable stainless steel (Column 6, lines 1-4; Column 10, lines 36-59). Fagan teaches that these alloys are exemplary because when bent, they will remain elastic through a greater range of stresses than prior guidewires. Since tensile yield stress and compressive yield stress are substantially less disproportionate, compressive failure is delayed, thus enabling the wire to be bent in a sharper curve without permanent deformation (Column 5, Lines 18-59). It would be obvious to one with ordinary skill in the art to use the teachings of Fagan to modify the invention of Fariabi to create a better-performing guidewire that will remain elastic through greater range of stresses. Fagan discloses in Column 10, lines 65-66, that the alloy can have a modulus of elasticity compared to that of type 304 stainless steel (approximately 28,000,000 to 29,000,000 psi.). In addition, the alloy can have a tensile strength as low as about 150 ksi, but preferably about 250 ksi. (Column 10, lines 63-66). Fagan teaches that the modulus of elasticity and the tensile strength depend on the degree to which it is desired to precipitation harden the alloy (Column 11, Lines 5-16) in order to create a guidewire with a smaller diameter without compromising performance. It would be obvious to one with ordinary skill in the art to use the teachings of Fagan to modify the invention of Fariabi in order to create a smaller diameter guidewire for better performance.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fariabi in view of Fagan, in further view of Reiss (WO 98/22024). Fariabi and Fagan teach all of the claimed limitations except a precipitation hardenable stainless steel essentially nickel free and a

precipitation hardenable stainless steel including less than about 1% nickel. Reiss discloses a guidewire (10) comprising an elongated core element (12) manufactured from a martensitic alloy that is heat-treated to render a fully hardened core throughout its cross sectional area (see Abstract). Reiss further discloses examples of temperature hardened, martensitic steel alloys such as carbon, manganese, chromium, silicone, molybdenum, iron, and nickel. As can be seen from page 7, Table II, line 9, the amount of nickel that can be used is negligible or in other words, essentially nickel-free or containing less than about 1% nickel. Reiss teaches nickel to be one of the hardened alloys used in guidewires having a hardened core having the characteristic of superior torsional control or torque transmission (Page 6, Lines 30-32 and Page 1, Lines 6-8). It would be obvious to one with ordinary skill in the art to use the teachings of Reiss to modify the invention of Fariabi and Fagan to create a guidewire that is essentially nickel-free or contains less than about 1% nickel in order for the guidewire to perform with superior torsional control or torque transmission.

Response to Arguments

Applicant's arguments filed March 29, 2004 have been fully considered but they are not persuasive. Applicant states that the prior art does not teach a flexible body disposed at a distal end of the distal section wherein the precipitation hardened material and superelastic material extend from the proximal section to at least substantially "underneath the flexible body." Examiner respectfully disagrees. When you hold the elongate member in a vertical position, with the distal section facing up and the proximal section facing down, the two materials are indeed "underneath the flexible body."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KLT Kelly

ANHTUAN T. NGUYEN
PRIMARY EXAMINER